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May 26, 1995

Dr. David C. Kennedy
2425 Third Avenue
San Diego, CA 92101

Dear Dr. Kennedy:

Children' fluoride supplements are marketed without the required New Drug Applications demonstrating safety and effectiveness. This situation exists as a result of manufacturers introducing products directly into the market prior to 1962 without seeking FDA approval. According to the FDA Office of Prescription Drug Compliance there are approximately 3,000 drugs in this category.

To deal with this problem the FDA established a program, "The Prescription Drug Rap Up" to evaluate these products and take appropriate regulatory action.

Unfortunately, FDA allows these products to remain on the market in the meantime, with estimates that the review could easily last ten more years. FDA's limited resources are devoted primarily to evaluating new products.

As a result, consumers, state and the federal government spend a fortune purchasing prescription drugs for which there is no evidence of effectiveness or safety.

Because of the vast number of published studies demonstrating the adverse effects of fluoride ingestion, I am confident the Federal Courts will force FDA to comply with the law and remove children's fluoride supplements from the market in a timely manner.

It should boggle one's mind that the inability to demonstrate the safety and effectiveness of fluoride supplements (marketed since the 1950's) to the FDA has gone unnoticed by those proposing fluoridating water, but after many years in the legislature nothing surprises me anymore.

Sincerely,

John V. Kelly

John V. Kelly
Assemblyman 36th District

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